

APPEAL TO THE BOARD OF PATENT APPEALS AND INTERFERENCES

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|------------------------------|---|---------------------------|
| In re Application of: |) | Confirmation No.: 4939 |
| Gary K. Michelson |) | |
| Serial No.: 10/674,971 |) | Group Art Unit: 3738 |
| Filed: September 30, 2003 |) | Examiner: David H. Willse |
| For: METHOD FOR INSERTING AN |) | |
| INTERBODY SPINAL FUSION |) | |
| IMPLANT HAVING AN |) | |
| ANATOMICALLY CONFORMED |) | |
| TRAILING END |) | |

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Sir:

APPEAL BRIEF

Real Party in Interest

The real party in interest is Warsaw Orthopedic, Inc. (hereinafter, the "Appellant"), the assignee of record for the above-identified application.

Related Appeals and Interferences

This application is a divisional of Application No. 09/792,679 ("679 application"), filed February 22, 2001. A Notice of Appeal and Request for Pre-Brief Appeal Conference were filed in the '679 application on July 1, 2011. On July 29, 2011, a Pre-Brief Appeal Conference Decision was mailed, indicating that Appellant must proceed with an appeal to the Board of Patent Appeals and Interferences.

Status of Claims

Claims 1-28, 60, and 61 have been cancelled. Claims 29-59 and 62-68 are pending, have been rejected, and are being appealed.

Status of Amendments

Appellant filed an Amendment After Final on May 16, 2011 ("Amendment"), amending independent claim 29. In the Advisory Action of June 1, 2011 ("Advisory

Action"), the Examiner acted on the amendment and entered it.

Summary of Claimed Subject Matter

There are two independent claims. Each is discussed below.

Independent claim 29 is directed to a method of inserting an artificial implant into a disc space between two adjacent vertebral bodies (e.g., Fig 6C). The method includes providing an artificial implant (100) having an upper surface (106) and a lower surface (108) (e.g., Fig. 7B). The implant has a lateral side and an opposite medial side and a maximum width therebetween (e.g., Fig. 7A). The upper and lower surfaces of the implant are arcuate from the lateral side to the medial side along the maximum width of said implant and in a plane transverse to a mid-longitudinal axis of the implant (e.g., Figs. 7A and 7B). The implant has generally non-linear leading (102) and trailing (104) ends (e.g., Figs. 6C and 7A). The mid-longitudinal axis of the implant, being perpendicular to and bisecting the maximum width into two equal parts, passes through the leading and trailing ends (e.g., Figs. 7A and 7B). The trailing end of the implant is configured to generally conform to at least a portion of the natural anatomical curvature of at least one of the anterior, posterior, and lateral aspects of the vertebral bodies (e.g., Fig. 6C). The implant has a length between the leading and trailing ends adapted to allow at least a portion of the implant proximate the leading end and at least a portion of the implant proximate the trailing end to each overlie respective portions of a peripheral rim of the densely compacted bone of the apophyseal rim along the anatomical curvature of the adjacent vertebral bodies when the implant is implanted in the disc space (e.g., Fig. 6C).

The method further includes forming an opening across a height of the disc space and into a portion of each of the adjacent vertebral bodies, the opening in the portion of each of the adjacent vertebral bodies being at least in part curved (e.g., Figs. 4 and 8).

The method further includes inserting, after the forming of the opening, the implant into the opening with the lateral side of the implant facing one of the anterior and lateral aspects of the vertebral bodies (e.g., Fig. 6B).

The method further includes positioning the leading end of the implant so that at least a portion of the implant proximate the leading end between the medial side and

the mid-longitudinal axis overlies the apophyseal rim without substantially protruding from the spine (e.g., Fig. 6C).

The method further includes positioning the trailing end of the implant so that at least a portion of the implant proximate the trailing end between the medial side and the mid-longitudinal axis overlies the apophyseal rim when said at least a portion of the implant proximate the leading end overlies the apophyseal rim without substantially protruding from the spine (e.g., Fig. 6C).

Independent claim 39 is directed to a method of inserting a pair of artificial implants into a disc space between two adjacent vertebral bodies (e.g., Fig 6C). The method includes providing a first artificial implant (100) having generally non-linear leading (102) and trailing (104) ends (e.g., Fig. 7A). The trailing end of the implant is configured to generally conform to at least a portion of the natural anatomical curvature of at least one of the anterior, posterior, and lateral aspects of the vertebral bodies (e.g., Fig. 6C). The first implant has a lateral side and an opposite medial side and a maximum width therebetween less than one half of the width of the disc space (e.g., Fig. 6C). The implant has a mid-longitudinal perpendicular to and bisecting the maximum width into two equal parts, which passes through the leading and trailing ends (e.g., 7A and 7B). The implant has a length between the leading and trailing ends adapted to allow at least a portion of the implant proximate the leading end and at least a portion of the implant proximate the trailing end to each overlie a peripheral rim of the densely compacted bone of the apophyseal rim along the anatomical curvature of the adjacent vertebral bodies when the first implant is implanted in the disc space (e.g., Fig. 6C). Each of the lateral and medial sides of the first implant are at least in part straight in a direction from the leading end to the trailing end along at least a portion of the length of the first implant (e.g., Figs. 7A and 6C).

The method further includes providing a second artificial implant (100) having generally non-linear leading (102) and trailing (104) ends being configured to generally conform to at least a portion of the natural anatomical curvature of at least one of the anterior, posterior, and lateral aspects of the vertebral bodies (e.g., Fig. 6C). The second

implant has a lateral side and an opposite medial side and a maximum width therebetween less than one half of the width of the disc space (e.g., Fig. 6C). The second implant has a mid-longitudinal axis perpendicular to and bisecting the maximum width into two equal parts, which passes through the leading and trailing ends (e.g., Fig. 6C). The second implant has a length between the leading and trailing ends adapted to allow at least a portion of the implant proximate the leading end and at least a portion of the implant proximate the trailing end to each overlie the peripheral rim of the densely compacted bone of the apophyseal rim along the anatomical curvature of the adjacent vertebral bodies when the second implant is implanted in the disc space (e.g., Fig. 6C). Each of the lateral and medial sides of the second implant are at least in part straight in a direction from the leading end to the trailing end along at least a portion of the length of the second implant (e.g., Fig. 6C).

The method further includes forming at least one opening across a height of the disc space and into a portion of each of the adjacent vertebral bodies, the at least one opening in the portion of each of the adjacent vertebral bodies being at least in part curved (e.g., Figs. 4 and 8).

The method further includes inserting, after the forming of the at least one opening, the first implant into the at least one opening with the lateral side facing one of the anterior and lateral aspects of the vertebral bodies (e.g., Fig. 6C).

The method further includes inserting, after the forming of the at least one opening, the second implant into the at least one opening with the lateral side of the second implant facing one of the anterior and lateral aspects of the vertebral bodies (e.g., Fig. 6C).

The method further includes positioning the leading end of each implant so that at least a portion of the implant proximate the leading end between the medial side and the mid-longitudinal axis overlies the apophyseal rim without substantially protruding from the spine (e.g., Fig. 6C).

The method further includes positioning the trailing end of each implant so that at least a portion of the implant proximate the trailing end between the medial side and the mid-longitudinal axis overlies the apophyseal rim when the at least a portion of the

implant proximate the leading end overlies the apophyseal rim without substantially protruding from the spine (e.g., Fig. 6C).

Grounds of Rejection to be Reviewed on Appeal

1. Claims 29, 30, 33-36, 39-41, 44-47, 50-59, 62, 63, and 65-67 are rejected under 35 U.S.C. § 102(b) over U.S. Patent No. 4,714,469 to Kenna ("Kenna");

2. Claims 31, 32, 42, 43, 64, and 68 are rejected under 35 U.S.C. § 103(a) over Kenna in view of U.S. Patent No. 5,192,327 to Brantigan ("Brantigan").

3. Claims 37, 38, 48, and 49 are rejected under 35 U.S.C. § 103(a) over Kenna in view of Publication No. WO 98/48738 to Crozet (via related U.S. Patent No. 6,855,168) ("Crozet").

Argument

Appellant submits the following arguments for consideration by the Board of Patent Appeals and Interferences:

I. Rejection under 35 U.S.C. § 102(b) over U.S. Patent No. 4,714,469 to Kenna.

The Supreme Court in *KSR International Co. v. Teleflex Inc. et al.* reaffirmed the framework for governing obviousness under 35 U.S.C. § 103(a) as set forth in *Graham et al. v. John Deere Co. of Kansas City et al.*, 383 U.S. 1 (1966). (See *KSR v. Teleflex*, 127 S.Ct. 1727 (2007).) The question of obviousness is resolved on the basis of factual determinations including: (1) the scope and content of the prior art, (2) the differences between the claimed invention and the prior art, (3) the level of ordinary skill in the pertinent art, and (4) where in evidence, so-called secondary considerations. (*Graham v. John Deere*, 383 U.S. at 17-18.) Even under *KSR v. Teleflex*, however, a combination of references that does not teach or suggest each and every element of the claimed invention cannot support a finding of obviousness.

According to the Federal Circuit, "a searching comparison of the claimed invention – including all its limitations – with the teachings of the prior art" is required of the Examiner when determining whether a claim is obvious. (*In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added).) As such, "obviousness requires a

suggestion of all limitations in a claim.” (*CFMT, Inc. v. YieldUP Int’l. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003); *citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974).)

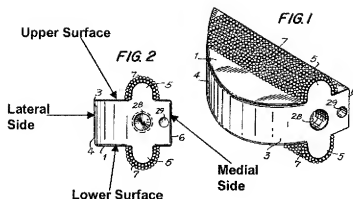
As discussed below, Appellant respectfully traverses the Examiner’s rejection at least because the asserted combination of references does not teach or suggest each and every limitation of the invention recited in independent claims 29 and 39. Thus, the asserted combination of references cannot support a finding of obviousness of independent claims 29 and 39 and claims dependent therefrom.

A. Independent claim 29 and dependent claims 30, 33-36, 50, 51, 54, 56, 58, 62, and 63.

1. Kenna does not disclose arcuate upper and lower surfaces “from the lateral side to the medial side along the maximum width.”

Independent claim 29 recites that “the upper and lower surfaces being arcuate from the lateral side to the medial side along the maximum width of said implant and in a plane transverse to a mid-longitudinal axis of the implant.” Kenna discloses an implant having “a first surface 1 and a second surface 2” (e.g., upper and lower surfaces, respectively); “curved portion 4” (e.g., lateral side); “straight side 6” (e.g., medial side); and arcuate “protuberances 5.” (See Kenna, col. 3, lines 34-35; 39, 55; Figs. 2 and 3.) Figs. 2 and 4 of Kenna show that upper and lower surfaces 1, 2 face up and down, respectively, while sides 4 and 6 face left and right, respectively. The Examiner contends that “lateral and medial sides as claimed may alternatively be viewed as including the upper and lower flat surface portions of the Kenna implant.” (Final Action, p. 2, lines 20-21.) The MPEP sets forth that the Examiner must use the “broadest reasonable interpretation.” (MPEP § 2111, p. 2100-37, col. 2 (Rev. 7, Sept. 2008) (emphasis added).) Moreover, the Federal Circuit recently held that “[w]hile the Board must give the terms their broadest reasonable construction, the construction cannot be divorced from the specification and the record evidence. (*In Re NTP, Inc.*, Appeal No. 2010-1243, p. 9 (Fed. Cir. Aug. 1, 2011) (*citing In re Suitco Surface*, 603 F.3d 1255, 1259 (Fed. Cir. 2010).)

Figs. 1 and 2 of Kenna are reproduced and annotated below to show the relevant elements.



Surfaces 1, 2, 4, and 6 are separate surfaces as described by Kenna. Surfaces 4, 6, are "sides," while surfaces 1, 2, are *prima facie* upper and lower surfaces because they are oriented at 90° to sides 4, 6 (see Figs. 1 and 2 above). Appellant respectfully submits that it is unreasonable to construe upper and lower facing surfaces that are oriented 90° to the sides as something other than an upper or lower surface, particularly when the claims treat these surfaces as separate elements, and the Kenna disclosure treats them as separate surfaces. Moreover, the Examiner's own language indicates that surfaces 1, 2 are better characterized as upper and lower surfaces rather than side surfaces. (See Final Action, page 2, line 21; and page 3, line 1.)

Fig. 2 of Kenna shows that arcuate protuberance 5 of upper and lower surfaces 1, 2 does not extend from curved side 4 to straight side 6. Accordingly, neither upper surface 1 nor lower surface 2 is arcuate "from the lateral side to the medial side along the maximum width of said implant and in a plane transverse to a mid-longitudinal axis of the implant" as recited in independent claim 29.

2. Kenna does not disclose "positioning the leading end."

Independent claim 29 further recites "positioning the leading end of the implant so that at least a portion of the implant proximate the leading end between the medial side and the mid-longitudinal axis overlies the apophyseal rim without substantially protruding from the spine." Kenna teaches that "[w]hen the grooves are drilled each drill bit is removed and replaced by a spacer to maintain the spaces between the vertebrae." (Kenna, col. 5, lines 66-68.) Kenna does not disclose or show that the leading ends of the implants are positioned such that portions of the implants proximate the leading end

between the medial side and the mid-longitudinal axis overlie the apophyseal rim. Accordingly, Kenna does not disclose this element of independent claim 29.

Appellant submits that independent claim 29 is allowable over Kenna, and that claims 30, 33-36, 50, 51, 54, 56, 58, 62, and 63, dependent from independent claim 29, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

B. Independent claim 39 and dependent claims 40, 44-47, 52, 53, 55, 57, 59, and 65-67.

1. Kenna does not disclose that each of the lateral and medial sides is "at least in part straight."

Independent claim 39 recites that "each of the lateral and medial sides" of the first and second implants is "at least in part straight in a direction from the leading end to the trailing end along at least a portion of the length" of the implant. The Examiner contends that "said upper and lower flat surface portions are straight along the implant length." (Final Action, p. 3, lines 1-2.) Claim 39 does not require the upper and lower surfaces to have the straight portion, but both of the medial and lateral sides to have the straight portion. Kenna fails to disclose this feature. Fig. 3 of Kenna shows that side 4 of the implant is curved and side 6 of the implant is straight. Accordingly, Kenna does not disclose an implant with lateral and medial sides as recited in independent claim 39.

2. Kenna does not disclose "positioning the leading end."

Independent claim 39 further recites "positioning the leading end of each implant so that at least a portion of the implant proximate the leading end between the medial side and the mid-longitudinal axis overlies the apophyseal rim without substantially protruding from the spine." Kenna teaches that "[w]hen the grooves are drilled each drill bit is removed and replaced by a spacer to maintain the spaces between the vertebrae." (Kenna, col. 5, lines 66-68). Fig. 4 of Kenna does not show that the leading ends of the implants are positioned such that portions of the implants proximate the leading end between the medial side and the mid-longitudinal axis overlie the apophyseal rim. Accordingly, Kenna does not disclose this element of independent claim 39.

Appellant submits that independent claim 39 is allowable over Kenna, and that claims 40, 44-47, 52, 53, 55, 57, 59, and 65-67, dependent from independent claim 39, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

C. Dependent claim 41.

Dependent claim 41, dependent from independent claim 39, recites "providing an implant with a symmetrical trailing end." Fig. 3 of Kenna shows that the trailing end of the implant is asymmetrical. The Examiner has provided no rationale to support the rejection of this claim. Accordingly, Appellant submits that claim 41 is independently patentable over Kenna.

II. Rejection under 35 U.S.C. § 103(a) over Kenna in view of U.S. Patent No. 5,192,327 to Brantigan.

A. Dependent claims 31 and 32.

Claim 31, dependent from independent claim 29, recites that the "implant is a fusion implant having a hollow therein, further comprising loading the implant with a fusion promoting material prior to inserting the implant."

The Examiner admits that "Kenna lacks openings communicating with a hollow space," and contends that "[t]o so modify Kenna [in view of Brantigan] would have been obvious in order to enhance the long-term stability." (See Final Action, p. 3, lines 4-8.) Appellant submits that the Examiner's rationale for making the combination falls short of the standard articulated in *KSR* because Kenna already accomplishes without modification what the Examiner states is the reason to combine the teachings of Kenna and Brantigan. (See, e.g., MPEP § 2141 (III), p. 2100-119, cols. 1-2 (Rev. 6, Sept. 2007) ("[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").) Kenna teaches that "placement of the implant between adjacent vertebrae tissue/bone ingrowth into the porous coating provides long-term stability." (Kenna, col. 4, lines 14-17 (emphasis added).) Thus, Appellant submits that one skilled in the art would not look to Brantigan for the reasons (e.g., enhanced stability) proposed by the Examiner when Kenna already

teaches an implant that provides long-term stability. Accordingly, Appellant submits that claim 31 is independently patentable over the proposed combination.

Appellant submits that dependent claim 32 is patentable at least due to its dependency from an allowable independent claim, or claims dependent therefrom.

B. Dependent claims 42 and 43.

Dependent claim 42, dependent from independent claim 39, recites that the "implant is a fusion implant having a hollow therein, further comprising loading the implant with a fusion promoting material prior to inserting the implant." Appellant submits that the proposed combination of Kenna in view of Brantigan cannot be maintained at least for the reasons set forth in Section II(A) above.

Appellant submits that dependent claim 43 is patentable at least due to its dependency from an allowable independent claim, or claims dependent therefrom.

C. Dependent claim 64.

Claim 64, dependent from independent claim 29, recites providing the implant with each of the upper and lower surfaces including "at least one opening adapted to communicate with one of the adjacent vertebral bodies, the openings in the upper and lower surfaces being in communication with one another and adapted to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through the implant."

The Examiner admits that "Kenna lacks openings communicating with a hollow space," and contends that "[t]o so modify Kenna [in view of Brantigan] would have been obvious in order to enhance the long-term stability." (See Final Action, p. 3, lines 4-8.) Appellant submits that the Examiner's rationale for making the combination falls short of the standard articulated in *KSR* because Kenna already accomplishes without modification what the Examiner states is the reason to combine the teachings of Kenna and Brantigan. (See, e.g., MPEP § 2141 (III), p. 2100-119, cols. 1-2 (Rev. 6, Sept. 2007) ("[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").) Kenna teaches that "placement of the implant between adjacent vertebrae tissue/bone ingrowth into the

porous coating provides long-term stability.” (Kenna, col. 4, lines 14-17 (emphasis added).) Thus, Appellant submits that one skilled in the art would not look to Brantigan for the reasons (e.g., enhanced stability) proposed by the Examiner when Kenna already teaches an implant that provides long-term stability. Accordingly, Appellant submits that claim 64 is independently patentable over the proposed combination.

D. Dependent claim 68.

Dependent claim 68, dependent from independent claim 39, recites “at least one opening adapted to communicate with one of the adjacent vertebral bodies, the openings in the upper and lower surfaces being in communication with one another and adapted to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through each respective implant.” Appellant submits that the proposed combination of Kenna in view of Brantigan cannot be maintained at least for the reasons set forth in Section II(C) above.

III. Rejection under 35 U.S.C. § 103(a) over Kenna in view of Publication No. WO 98/48738 to Crozet (via related U.S. Patent No. 6,855,168).

A. Dependent claim 37.

Dependent claim 37, dependent from independent claim 29, recites “rotating the implant at least one half turn into the opening.”

1. The proposed combination does not teach or suggest each and every claim element.

Appellant disagrees with the Examiner’s contention that a “screw or screws spanning the disc space and threadingly engaging adjacent vertebrae, as taught in Crozet . . . would have been an obvious supplement or substitute for the protuberances 5 of Kenna.” (Final Action, p. 3, lines 17-20 (emphasis added).) Appellant submits that even if a portion of the implant of Kenna was modified as proposed by the Examiner to include a screw or screws, the implant itself would be inserted into the space linearly and such insertion of the modified Kenna implant would not include “rotating the implant at least one half turn into the opening” as recited in dependent claim 37. Thus, the proposed combination would not result in Appellant’s claimed invention.

2. There is no rationale to combine Kenna and Crozet because Kenna already achieves, without modification, what the Examiner states is the reason to combine.

The Examiner proposes to substitute protuberances 5 of Kenna with the anchorage reinforcement member of Crozet to "improve anchorage and to promote bone fusion." (See Final Action, p. 3, lines 17-21.) Appellant submits that the Examiner's rationale for making the combination falls short of the standard articulated in *KSR* at least because Kenna already teaches that protuberances 5 provide "rotational stability" and "adequate bone ingrowth to stabilize the vertebrae." (See Kenna, col. 4, lines 6-7 and 23.) In discussing whether a combination would have worked for its intended purpose, the *2010 KSR Guidelines Update* states that "[a]n inference that a claimed combination would not have been obvious is especially strong where the prior art's teachings undermine the very reason being proffered as to why a person of ordinary skill would have combined the known elements."¹ Accordingly, Appellant submits that claim 37 is independently patentable over the proposed combination.

3. Kenna and Crozet teach away from one another.

Kenna discloses an implant that is inserted linearly between two adjacent vertebral bodies and having upper and lower surfaces 1, 2 with elongated protuberances 5 that "extend anterior to posterior, [and] provide rotational stability." (Kenna, col. 3, lines 52-53; col. 4, 22-23 (emphasis added).) Conversely, Crozet discloses an anchorage reinforcement member 20 that is inserted into the vertebral bodies by rotation. (See, e.g., Crozet, col. 10, lines 2-4.) Furthermore, Kenna expressly teaches away from rotating/screwing in the implant by disclosing that positioning tool includes a locking key that "prevents rotation of the implant about the axis of the positioning tool." (Kenna, col. 5, lines 17-18 (emphasis added).) Accordingly, Kenna teaches away from the disclosure of Crozet.²

¹ *2010 KSR Guidelines Update*, Federal Register, Vol. 75, No. 169, p. 53659 (September 1, 2010) (teaching point using *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314 (Fed. Cir. 2009)).

² MPEP §2141.02(VI), "Prior Art Must Be Considered In Its Entirety, Including Disclosures That Teach Away From The Claims," page 2100-126, col. 1 (Rev. 6, Sept. 2007).

4. The proposed combination would lead to unpredictable results and cannot be properly sustained.

The rationale used by the Examiner to support the combination of Kenna and Crozet does not yield predictable results. In the Office Action, the Examiner states that a "screw of screws . . . as taught in Crozet . . . would have been an obvious supplement or substitute for the protuberances 5 of Kenna." (Final Action, page 3, lines 17-20.) Per the 2010 KSR Guidelines Update, (and MPEP § 2143(A)(3)), "a proper rejection based on the rationale that the claimed invention is a combination of prior art elements also includes a finding that results flowing from the combination would have been predictable to a person of ordinary skill in the art. (Citation omitted). If results would not have been predictable, Office personnel should not enter an obviousness rejection using the combination of prior art elements rationale, and should withdraw such a rejection if it has been made."³

Appellant submits that modifying the implant of Kenna, which has a curved leading end (see, e.g., Kenna, Fig. 4), to incorporate the cylindrical threaded anchorage reinforcement member 20 of Crozet (which has a flat leading end; see, e.g., Crozet, Fig. 28) for the purpose proposed by the Examiner would lead to unpredictable results. For example only, in order to maintain a continuous leading end curvature created by Kenna, one would have to somehow design the leading end of the Crozet threaded cylinder (20) to match the curvature at the precise moment when the cylinder is fully installed. Accordingly, Appellant submits that the rejection cannot be properly sustained.

B. Dependent claim 38.

Dependent claim 38, dependent from independent claim 29, recites "screwing the implant into the at least one opening."

1. The proposed combination does not teach or suggest each and every claim element.

Appellant disagrees with the Examiner's contention that a "screw or screws spanning the disc space and threadingly engaging adjacent vertebrae, as taught in Crozet . . . would have been an obvious supplement or substitute for the protuberances

³ 2010 KSR Guidelines Update, Federal Register, Vol. 75, No. 169, p. 53647 (September 1, 2010).

5 of Kenna." (Final Action, p. 3, lines 17-20 (emphasis added).) Appellant submits that even if a portion of the implant of Kenna was modified as proposed by the Examiner to include a screw or screws, the implant itself would be inserted into the space linearly and such insertion of the modified Kenna implant would not include "screwing the implant into the opening" as recited in dependent claim 38. Thus, the proposed combination would not result in Appellant's claimed invention. Furthermore, Kenna expressly teaches away from rotating/screwing in the implant by disclosing that positioning tool includes a locking key that "prevents rotation of the implant about the axis of the positioning tool." (Kenna, col. 5, lines 17-18 (emphasis added).)

2. There is no rationale to combine Kenna and Crozet because Kenna already achieves, without modification, what the Examiner states is the reason to combine.

The Examiner proposes to substitute protuberances 5 of Kenna with the anchorage reinforcement member of Crozet to "improve anchorage and to promote bone fusion." (See Final Action, p. 3, lines 17-21.) Appellant submits that the Examiner's rationale for making the combination falls short of the standard articulated in *KSR* at least because Kenna already teaches that protuberances 5 provide "rotational stability" and "adequate bone ingrowth to stabilize the vertebrae." (See Kenna, col. 4, lines 6-7 and 23.) Accordingly, Appellant submits that claim 38 is independently patentable over the proposed combination.

C. Dependent claim 48.

Dependent claim 48, dependent from independent claim 39, recites "rotating the implant at least one half turn into the at least one opening." Appellant submits that dependent claim 48 is patentable over the proposed combination of Kenna in view of Crozet at least for the reasons set forth in Section III(A) above.

D. Dependent claim 49.

Dependent claim 49, dependent from independent claim 39, recites "screwing the implant into the at least one opening." Appellant submits that dependent claim 49 is patentable over the proposed combination of Kenna in view of Crozet at least for the reasons set forth in Section III(B) above.

Conclusion

Appellant respectfully submits that independent claims 29 and 39 are patentable and that dependent claims 30-38, 40-59, and 62-68, dependent from one of independent claims 29 and 39, are patentable at least due to their dependency from an allowable independent claim. Appellant respectfully requests the Board to reverse the Examiner's rejections and allow claims 29-59 and 62-68.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this Appeal Brief, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,
MARTIN & FERRARO, LLP

Dated: August 18, 2011

By: _____



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CLAIMS APPENDIX

Claims 1-28 (cancelled).

29. A method of inserting an artificial implant into a disc space between two adjacent vertebral bodies, the method comprising:

providing an artificial implant having an upper surface and a lower surface, the implant having a lateral side and an opposite medial side and a maximum width therebetween, the upper and lower surfaces being arcuate from the lateral side to the medial side along the maximum width of said implant and in a plane transverse to a mid-longitudinal axis of the implant, the implant having generally non-linear leading and trailing ends, the mid-longitudinal axis of the implant passing through said leading and trailing ends, the mid-longitudinal axis being perpendicular to and bisecting the maximum width into two equal parts, the trailing end being configured to generally conform to at least a portion of the natural anatomical curvature of at least one of the anterior, posterior, and lateral aspects of the vertebral bodies, the implant having a length between the leading and trailing ends adapted to allow at least a portion of the implant proximate the leading end and at least a portion of the implant proximate the trailing end to each overlie respective portions of a peripheral rim of the densely compacted bone of the apophyseal rim along the anatomical curvature of the adjacent vertebral bodies when the implant is implanted in the disc space;

forming an opening across a height of the disc space and into a portion of each of the adjacent vertebral bodies, the opening in the portion of each of the adjacent vertebral bodies being at least in part curved;

inserting, after the forming of the opening, the implant into the opening with the lateral side of the implant facing one of the anterior and lateral aspects of the vertebral bodies;

positioning the leading end of the implant so that at least a portion of the implant proximate the leading end between the medial side and the mid-longitudinal axis overlies the apophyseal rim without substantially protruding from the spine; and

positioning the trailing end of the implant so that at least a portion of the implant proximate the trailing end between the medial side and the mid-longitudinal axis overlies the apophyseal rim when said at least a portion of the implant proximate the leading end overlies the apophyseal rim without substantially protruding from the spine.

30. The method of claim 29, further comprising attaching a driver instrument to the implant to insert the implant into the opening formed during the step of forming.
31. The method of claim 29, wherein the implant is a fusion implant having a hollow therein, further comprising loading the implant with a fusion promoting material prior to inserting the implant.
32. The method of claim 31, wherein the fusion promoting material includes at least one of bone, coral, bone morphogenetic protein, and genes coding for the production of bone.
33. The method of claim 29, further comprising combining the implant with a fusion promoting material.
34. The method of claim 33, wherein the fusion promoting material includes at least one of bone, coral, bone morphogenetic protein, and genes coding for the production of bone.
35. The method of claim 29, wherein the forming of the opening includes drilling the opening.
36. The method of claim 29, wherein the inserting of the implant includes linearly inserting the implant into the opening.
37. The method of claim 29, wherein the inserting of the implant includes rotating the implant at least one half turn into the opening.
38. The method of claim 29, wherein the inserting of the implant includes screwing the implant into the opening.

39. A method of inserting a pair of artificial implants into a disc space between two adjacent vertebral bodies, the method comprising:

providing a first artificial implant having generally non-linear leading and trailing ends, the trailing end being configured to generally conform to at least a portion of the natural anatomical curvature of at least one of the anterior, posterior, and lateral aspects of the vertebral bodies, the first implant having a lateral side and an opposite medial side and a maximum width therebetween less than one half of the width of the disc space, the implant having a mid-longitudinal axis passing through said leading and trailing ends, the mid-longitudinal axis being perpendicular to and bisecting the maximum width into two equal parts, and a length between the leading and trailing ends adapted to allow at least a portion of the implant proximate the leading end and at least a portion of the implant proximate the trailing end to each overlie a peripheral rim of the densely compacted bone of the apophyseal rim along the anatomical curvature of the adjacent vertebral bodies when the first implant is implanted in the disc space, each of the lateral and medial sides being at least in part straight in a direction from the leading end to the trailing end along at least a portion of the length of the first implant;

providing a second artificial implant having generally non-linear leading and trailing ends being configured to generally conform to at least a portion of the natural anatomical curvature of at least one of the anterior, posterior, and lateral aspects of the vertebral bodies, the second implant having a lateral side and an opposite medial side and a maximum width therebetween less than one half of the width of the disc space, the implant having a mid-longitudinal axis passing through said leading and trailing ends, the mid-longitudinal axis being perpendicular to and bisecting the maximum width into two equal parts, and a length between the leading and trailing ends adapted to allow at least a portion of the implant proximate the leading end and at least a portion of the implant proximate the trailing end to each overlie the peripheral rim of the densely

compacted bone of the apophyseal rim along the anatomical curvature of the adjacent vertebral bodies when the second implant is implanted in the disc space, each of the lateral and medial sides being at least in part straight in a direction from the leading end to the trailing end along at least a portion of the length of the second implant;

forming at least one opening across a height of the disc space and into a portion of each of the adjacent vertebral bodies, the at least one opening in the portion of each of the adjacent vertebral bodies being at least in part curved;

inserting, after the forming of the at least one opening, the first implant into the at least one opening with the lateral side facing one of the anterior and lateral aspects of the vertebral bodies;

inserting, after the forming of the at least one opening, the second implant into the at least one opening with the lateral side of the second implant facing one of the anterior and lateral aspects of the vertebral bodies;

positioning the leading end of each implant so that at least a portion of the implant proximate the leading end between the medial side and the mid-longitudinal axis overlies the apophyseal rim without substantially protruding from the spine; and

positioning the trailing end of each implant so that at least a portion of the implant proximate the trailing end between the medial side and the mid-longitudinal axis overlies the apophyseal rim when the at least a portion of the implant proximate the leading end overlies the apophyseal rim without substantially protruding from the spine.

40. The method of claim 39, wherein the providing of at least one of the implants includes providing an implant with an asymmetrical trailing end.
41. The method of claim 29, wherein the providing of the implant includes providing an implant with a symmetrical trailing end.

42. The method of claim 39, wherein each implant is a fusion implant having a hollow therein, further comprising loading each implant with fusion promoting material prior to inserting each implant.
43. The method of claim 42, wherein the fusion promoting material includes at least one of bone, coral, bone morphogenetic protein, and genes coding for the production of bone.
44. The method of claim 39, further comprising combining at least one of the implants with a fusion promoting material.
45. The method of claim 44, wherein the fusion promoting material includes at least one of bone, coral, bone morphogenetic protein, and genes coding for the production of bone.
46. The method of claim 39, wherein the forming of the opening includes drilling the at least one opening.
47. The method of claim 39, wherein each insertion includes linearly inserting the implant into the at least one opening.
48. The method of claim 39, wherein each insertion includes rotating the implant at least one half turn into the at least one opening.
49. The method of claim 39, wherein each insertion includes screwing the implant into the at least one opening.
50. The method of claim 29, wherein the positioning of the implant includes positioning a majority of the trailing end of the implant along the apophyseal rim of at least one of the adjacent vertebral bodies.
51. The method of claim 29, wherein the providing of the implant includes providing the trailing end of the implant with a curved portion generally corresponding to the natural curvature of at least one of the anterior and lateral aspects of the vertebral bodies.
52. The method of claim 39, wherein the positioning of each implant includes positioning a majority of the trailing end of each implant along the apophyseal rim of at least one of the adjacent vertebral bodies.

- 53. The method of claim 39, wherein the providing of at least one of the implants includes providing the trailing end of at least one of the implants with a curved portion generally corresponding to the natural curvature of at least one of the anterior and lateral aspects of the vertebral bodies.
- 54. The method of claim 29, wherein the positioning of the implant includes positioning the entire trailing end of the implant on the peripheral rim of the densely compacted bone along the anatomical curvature of the adjacent vertebral bodies.
- 55. The method of claim 39, wherein the positioning of each implant includes positioning the entire trailing end of each implant on the peripheral rim of the densely compacted bone along the anatomical curvature of the adjacent vertebral bodies.
- 56. The method of claim 29, wherein the positioning of the implant includes positioning at least a portion of the trailing end of the implant between the medial side and the mid-longitudinal axis of the implant on at least one of the anterior cortex and apophyseal rim of the adjacent vertebral bodies.
- 57. The method of claim 39, wherein the positioning of each implant includes positioning at least a portion of the trailing end of each implant between the medial side and the mid-longitudinal axis of the implant on at least one of the anterior cortex and apophyseal rim of the adjacent vertebral bodies.
- 58. The method of claim 29, wherein the providing of the implant includes providing the implant with a first maximum length measured along the medial side that is longer than a second maximum length measured along the lateral side.
- 59. The method of claim 39, wherein the providing of each implant includes providing each implant with a first maximum length measured along the medial side that is longer than a second maximum length measured along the lateral side.

Claims 60 and 61 (cancelled).

62. The method of claim 29, wherein the providing of the implant includes providing the implant with at least in part arcuate upper and lower surfaces extending from the lateral side to the medial side of the implant.
63. The method of claim 29, wherein the providing of the implant includes providing the implant with upper and lower surfaces each having an arcuate portion extending across the mid-longitudinal axis of the implant.
64. The method of claim 29, wherein the providing of the implant includes providing the implant with each of the upper and lower surfaces including at least one opening adapted to communicate with one of the adjacent vertebral bodies, the openings in the upper and lower surfaces being in communication with one another and adapted to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through the implant.
65. The method of claim 39, wherein each of the implants provided include upper and lower surfaces that are each arcuate along a vertical plane transverse to the mid-longitudinal axis of each respective implant.
66. The method of claim 39, wherein each of the implants provided include upper and lower surfaces that each include an arcuate portion extending from the lateral side to the medial side of each respective implant.
67. The method of claim 39, wherein each of the implants provided include upper and lower surfaces that have an arcuate portion extending across the mid-longitudinal axis of each respective implant.
68. The method of claim 39, wherein each of the implants provided include upper and lower surfaces that include at least one opening adapted to communicate with one of the adjacent vertebral bodies, the openings in the upper and lower surfaces being in communication with one another and adapted to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through each respective implant.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.